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10/567,508	02/07/2006	Jason Reynolds	047956306612	6492

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EXAMINER

HORNBERGER, JENNIFER LEA

ART UNIT	PAPER NUMBER
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3734

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10/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,508	Applicant(s) REYNOLDS ET AL.	
	Examiner JENNIFER L. HORNBERGER	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-44, 46-60 and 88-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-44, 46-60 and 88-96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/20/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 33, 34, 43, 46, 48-50, 54-57, and 88-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acosta et al. (US 7,137,993) in view of Kujawski (US 4,795,434).

Regarding claims 33, 57, 88, 91, 94, and 95, Acosta et al. disclose a device for allowing a user to deploy a plurality of therapeutic medical appliances in an anatomical lumen of a patient, the device comprising: a longitudinally extending outer tubular member (380) having distal and proximal ends and an interior and exterior surface, the outer tubular member defines a lumen longitudinally extending substantially the distance from the distal end to the proximal end of the outer tubular member and forming a longitudinal expanse there between, and the outer tubular member having a tip coupled with the distal end; a sheath (184) complementary and slidably coupled with the outer tubular member such that the sheath and the outer tubular member are linearly displaceable with respect to the other, the sheath having proximal and distal ends and a plurality of tabs spaced a functional distance apart from one another between

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the proximal and distal ends thereof, the tabs (376, 378) facing toward the lumen of the outer tubular member, wherein each tab is configured to engage at least one therapeutic medical appliance; and a handle, coupled with a portion of the outer tubular member, the handle (18) having first and second ends (Fig. 43A-B).

Acosta et al. fail to disclose a plurality of tracks independent of one another and the outer tubular member, each of the tracks having a plurality of axially spaced tabs with respect to the embodiment of figures 43A-B. Acosta et al. disclose an alternative embodiment (Fig. 45A-C) which includes a track (375) comprising a plurality of tabs (408) on a semi-tube (406), the semi-tube movable with respect to a track which comprises a plurality of tabs (402) on a sheath (184). The movement of the semi-tube with respect to the sheath (184) is used instead of a pusher member (as used in the embodiment of Fig. 43A-B; col. 26, ln. 50 - col. 27, ln. 30) for advancing and deploying a desired number of prostheses (col. 28, ln. 1-30). It would have been obvious to one of ordinary skill in the art to substitute the pusher tube (186) disclosed by Acosta et al. with respect to figures 43A-B with the pusher tube configuration of figures 45A-C by modifying the sheath (184) to form two semi-tubes or "tracks" each having a plurality of tabs as suggested by Acosta et al., wherein the semi-tubes are independent of each other and the outer sheath, such that one of the semi-tubes can be moved with respect to the other within the outer sheath to achieve the same predictable result of advancing the desired number of prosthesis into the outer sheath (380). Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

Acosta et al. fail to disclose a plurality of grooves running parallel to the longitudinal expanse. Kujawski discloses an outer tube (17) having a plurality of longitudinal grooves (37) through which ears (36) slide (col. 4, ln. 57-66, Fig. 7). It would have been obvious to one of

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ordinary skill in the art to provide grooves along the inner surface of the length of the outer tube and ears or projections on the tracks of Acosta et al. to provide the tracks with controlled, rotationally fixed linear sliding motion as taught by Kujawski.

Regarding claim 34, Acosta et al. disclose at least one radially self-expanding therapeutic medical appliance (182) carried between tabs of the plurality of tracks, within the lumen of the outer tubular member (380) and thereby maintained in the radially contracted state (col. 28, ln.34-40).

Regarding claim 43, Acosta et al. disclose the distal tip comprises an interior and an exterior surface and distal and proximal ends, where the distal tip is taken to be the distal end of the outer tube.

Regarding claim 46, Acosta et al. in view of Kujawski the distal tip further comprises utility grooves formed along the exterior surface thereof, which extend substantially between the distal and proximal ends thereof.

Regarding claim 48, Acosta et al. disclose the outer tubular member when moved longitudinally relative to the track members in a proximal direction away from the selected location, releases the therapeutic medical appliance for radial self-expansion (col. 27, ln. 9-12).

Regarding claim 49, Acosta et al. disclose wherein there are at least two therapeutic medical appliances (col. 5, ln. 34-35).

Regarding claim 50, Acosta et al. disclose the outer tubular member (380) when moved longitudinally relative to the track members in a proximal direction away from the selected location, releases the distal most therapeutic medical appliance (182') for radial self-expansion and places the distally penultimate therapeutic medical appliance in a ready deployment position within the outer tubular member lumen (col. 27, ln. 9-12).

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Regarding claim 54, Acosta et al. disclose the outer tubular member is kink resistant (col. 11, ln. 55-62).

Regarding claim 55, Acosta et al. disclose the handle has a safety means that prevents premature deployment of the at least one therapeutic medical appliance, in the sense that the handle comprises a means for controlling the surgeon to control the advancing means which is used to deploy the therapeutic appliance when the surgeon is ready (col. 12, ln. 3-8, col. 7, ln. 50-67).

Regarding claim 56, Acosta et al. disclose the tabs prevent the uncontrolled proximal migration of the therapeutic medical appliance.

Regarding claims 89, 90, 92, 93, and 96, Acosta et al. in view of Kujawski disclose each therapeutic medical appliance is configured to be engaged by a plurality of tabs at both a proximal and distal end thereof (Fig. 45A).

4. Claims 35-42, 44, 47 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acosta et al. (US 7,137,993) in view of Kujawski (US 4,795,434) as applied to claim 33 or 43 above, and further in view of Kucharczyk et al. (US 6,626,902).

Regarding claim 35, Acosta et al. fail to disclose the outer tubular member defines longitudinally extending channels formed between the exterior and interior surfaces thereof. Kucharczyk et al. disclose an outer tubular member comprising a plurality of longitudinally extending channels formed between the exterior and interior surfaces of the outer tubular member (Figures 1 and 2) allowing multiple separate and distinct functions at the distal of the catheter without the removal of elements or replacement of the catheter (col. 10, ln. 30-34). Therefore, it would have been obvious to one of ordinary skill in the art to provide longitudinally extending channels in the device of Acosta et al. to allow multiple instruments to be

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simultaneously delivered to and used at the distal end of the catheter as suggested by Kucharczyk et al.

Regarding claim 36, Acosta et al. in view of Kucharczyk et al. disclose the longitudinally extending channels accommodate utility instruments through a lumen thereof.

Regarding claim 37-42, Acosta et al. in view of Kucharczyk et al. disclose the utility instruments are selected from the group consisting of guidewires having ultrasound and optical capabilities, optical devices, syringe systems or combinations thereof, wherein the syringe system is capable of administering an adhesive.

Regarding claims 44, Acosta et al. fail to disclose the distal tip further comprises a light source. Kucharczyk et al. disclose an outer tubular member comprising a plurality of longitudinally extending channels for delivering tools such as optical fibers to the distal end of the catheter (col. 10, ln. 30-34 and col. 11, ln. 1-2). It would have been obvious to provide fiber optic viewing fibers and a light piping fiber in the device of Acosta et al. to allow the surgeon to view the treatment site and to confirm proper placement of the therapeutic appliance. It follows, that the distal tip of the device of Acosta et al. would further comprise optic viewing fibers and a light source.

Regarding claim 47, Acosta et al. fail to disclose the distal tip comprises a plurality of apertures formed therethrough. Kucharczyk et al. disclose an outer tubular member comprising a plurality of longitudinally extending channels formed between the exterior and interior surfaces of the outer tubular member (Figures 1 and 2) allowing multiple separate and distinct functions at the distal of the catheter without the removal of elements or replacement of the catheter (col. 10, ln. 30-34). Therefore, it would have been obvious to one of ordinary skill in the art to provide a longitudinally extending channels in the device of Acosta et al. to allow multiple instruments to be simultaneously delivered to and used at the distal end of the catheter as suggested by

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Kucharczyk et al. Acosta et al. in view of Kucharczyk et al. the distal tip defines a plurality of apertures formed there through (Fig. 2).

Regarding claim 52, Acosta et al. in view of Kucharczyk et al. the longitudinally extending channels of the outer tubular member is configured to receive an optical scope.

5. Claim 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Acosta et al. (US 7,137,993), Kujawski (US 4,795,434), and Kucharczyk et al. (6,626,902) as applied to claim 37 above, and further in view of Fischell et al. (US 5,735,859).

Regarding claim 51, Acosta et al. disclose the guidewire introduced through the proximal end of the device. Fischell et al. disclose a guidewire is introduced through a portion of the exterior diameter of the outer tubular member of a balloon catheter in alternative to an over the wire balloon catheter (col. 3, ln. 48-53). It would have been obvious to one of ordinary skill to modify the device of Acosta et al. to so that the guide wire is introduced through a portion of the exterior of the outer tubular member to allow rapid exchange of catheters.

6. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Acosta et al. (US 7,137,993) and Kujawski (US 4,795,434) as applied to claim 33 above, and further in view of Mikus et al. (US 6,416,545).

Regarding claim 53, Acosta et al. fails to disclose the outer tubular member is clear. Mikus et al. disclose outer sheath (13) is transparent (col. 8, ln. 10-11). It would have been obvious to one of ordinary skill in the art to make the outer sheath of Acosta et al. to allow the surgeon to see therapeutic appliances with an endoscope or other optical device and to determine the number left within the sheath.

7. Claim 58-60 rejected under 35 U.S.C. 103(a) as being unpatentable over Acosta et al. (US 7,137,993) and Kujawski (US 4,795,434) as applied to claim 57 above, and further in view of Sauer et al. (5,503,635).

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Regarding claim 58, Acosta et al. fail to disclose a therapeutic medical appliance retaining housing is reversibly coupled about the distal end of the device. However, Sauer et al. disclose the handle being selectively detachable from the endoscopic section so that either piece may be disposed of or sterilized and reused. Therefore, it would have been obvious to one of ordinary skill in the art to make the housing reversibly coupled to the device so that the device could be sterilized and reused as suggested by Sauer et al.

Regarding claim 59, Acosta et al. disclose the housing contains one or more therapeutic medical appliances (col. 5, ln. 34-35).

Regarding claim 60, Acosta et al. disclose the tabs prevent the uncontrolled proximal migration of the therapeutic medical appliance.

Response to Arguments

8. Applicant argues that neither of the embodiments disclosed by Acosta et al. in figures 43A and 45A-E comprise a plurality of tracks complementary and slidably coupled with the grooves of an outer tubular member such that the tracks and the grooves are linearly displaceable with respect to the other and each track comprising a plurality of spaced tabs. The examiner agrees that neither of the embodiments taken individually disclose a plurality of tracks complementary and slidably coupled with the grooves of an outer tubular member such that the tracks and the grooves are linearly displaceable with respect to the other and each track comprising a plurality of spaced tabs.

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The embodiment of 45A-E depicts the action of moving the slidable member (375) and associated tabs relative to the sheath (184) and its associated tabs to advance the prosthesis from the area between the opposing tabs (col. 28, ln. 1-30). It is the examiner's position that one of ordinary skill would recognize that the pusher member (186) of the embodiment of 43A could be replaced by modifying the sheath to comprise two independently sliding tracks (such as semi-tubes) such that one track can be held stationary while the other is moved, and each of the tracks having plurality of tabs. This substitution would accomplish the same predictable result of advancing the prosthesis into the outer member (380). Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh

10/08/2009

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734